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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/620,317

07/15/2003

Yunping Li

BBRI-2008US01

7947

7590

08/03/2006

Kevin M. Farrell
Pierce Atwood
Suite 350
One New Hampshire Avenue
Portsmouth, NH 03801

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,317

Applicant(s)

LI ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Response filed May 22, 2006 is acknowledged. Claims 1-11 remain under consideration. Independent claims 1 and 5 are presently limited to the kinase inhibitors U0126, PD98059 and PD18432. A Declaration under 37 CFR 1.132 filed May 22, 2006 is further acknowledged.

In the last Office Action it was asserted the title of the invention is not descriptive because it was not clearly indicative of the invention to which the claims are directed. The abstract of the disclosure was also objected to because the abstract is no longer limited to the subject matter that is presently claimed. No indication of an amendment to the abstract is noted. Accordingly, the objection to the disclosure is maintained.

In the last Office Action claims 1-12 and 16-19 were rejected under 35 U.S.C. 102(a) as being anticipated by Li et al., Anesthesiology.

In response a Declaration under 37 CFR 1.132 by Kathleen Morgan has been submitted. The Declaration incorrectly states that the outstanding Office Action is based on the Examiner's impression that the invention was conceived by an inventive entity other than those named in the instant application. Ms. Morgan further asserts the rejection of record under 35 U.S.C. 102(a) is based on the belief that all of the named persons in Li et al., Anesthesiology, had conceived aspects of the invention as claimed.

This is an incorrect characterization of the Office Action. The Examiner makes no claim as to who conceived aspects of the present invention or who contributed whatever subject matter to the reference. Taken as a whole, the reference was applied because it teaches the subject matter of claims 1-11. Eliminating Sabah Malek and Hyun-Dong Je as contributors of the present invention appears to be the intention of the

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submitted Declaration. Because this is clearly stated by Applicants' attorney on page 6 of the Response filed May 22, 2006, a corrected Declaration is not needed.

In view of the Declaration, the rejection of record under 35 U.S.C. 102(a) is withdrawn.

Claims 1-11 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims were directed to the prevention or delaying of preterm uterine contractions in a pregnant mammal comprising administering a compound that inhibits kinase activity such that a decrease in the levels of both phosphorylated ERK and phosphorylated caldesmon in the pregnant mammal is achieved.

Subsequent to the deletion of the term "preventing", this rejection of record is withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nohara et al., Biochemical and Biophysical Research Communications.

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Nohara teaches the administration of the MEK inhibitor PD98059 to cultured pregnant rat uterine cells obtained at day 21 before the onset of labor (preterm). Pretreatment of cells with this MEK inhibitor completely inhibited both oxytocin- and EGF-induced tyrosine phosphorylation of MAP kinase. See Figure 2A where PD98059 immediately inhibited the oxytocin-induced uterine contraction as compared to non-administration of the MEK inhibitor. See page 942, lines 9-11.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nohara et al., Biochemical and Biophysical Research Communications, in view of Oldenhof et al., Am. J. Physiology.

Nohara teaches the administration of the MEK inhibitor PD98059 to cultured pregnant rat uterine cells obtained at day 21 before the onset of labor (preterm). Pretreatment of cells with this MEK inhibitor completely inhibited both oxytocin- and EGF-induced tyrosine phosphorylation of MAP kinase. See Figure 2A where PD98059 immediately inhibited the oxytocin-induced uterine contraction as compared to non-administration of the MEK inhibitor. See page 942, lines 9-11. Nohara fails to mention the selective MAPK inhibitor U-0126. However, Oldenhof teaches the inhibitors PD-98059 and U-0126 as exhibiting essentially equivalent activity with respect to MAPK inhibition, specificity to the ERK pathway and to their response to stretch (as that

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imposed on the uterine wall by a growing fetus). Oldenhof teaches a role for mechanical factors in the induction of MAPK activity in the pregnant myometrium. Therefore, in view of the combined teachings of Nohara and Oldenhof, one skilled in the obstetrical art would have been motivated to administer a MAPK inhibitor such as PD-98059 or U-126 to delay preterm uterine contractions. Such would have been obvious in the absence of evidence to the contrary because the prior art references teach an inhibition of preterm uterine contractions following the administration compounds such as PD-98059 and U-1026 that inhibit the activity of the mitogen-activated protein kinase enzyme system.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 29, 2006

Phyllis Spivack
Phyllis Spivack
PHYLLIS SPIVACK
1614 **PRIMARY EXAMINER**